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BIOMÉRIEUX

510(k) SUMMARY

Coag-A-Mate MTX® III

510(k) Submission Information: K051030

Submitter's Name:	bioMérieux, Inc.
Address:	100 Rodolphe Durham, NC 27712
Contact Person:	John Cusack Sr. Regulatory Affairs Specialist
Phone Number:	919-620-2803
Fax Number:	919-620-2548
Date of Preparation:	December 18, 2005

B. Device Name:

Formal/Trade Name:	Coag-A-Mate MTX® III
Classification Name:	21 CFR 864.5425 Multipurpose System for In Vitro Coagulation Studies
Common Name:	Coag-A-Mate MTX® III

C. Predicate Device: Coag-A-Mate MTX® II (K962857), MDA® 180 (K924453)

D. 510(k) Summary:

Intended Use and Description

The COAG-A-MATE MTX III intended use is a multipurpose system for in vitro diagnostic coagulation studies and capable of performing clotting, chromogenic, and immunoassays within various populations.

The assays used with the Coag-A-Mate MTX III are generally used for as following: 1) Screening patients for Hemostasis abnormalities. 2) Pre-surgical screening. 3) Monitoring anticoagulant therapy with coumadin and or heparin. 4) Monitoring bleeding disorders such as Hemophilia or vWD. 5) Monitoring patients with DIC. 6) Monitoring and the evaluation of patients suspected of venous thromboembolism (VTE), which is comprised of deep vein thrombosis (DVT) and pulmonary embolism (PE).

Technical Logical Differences

The technological characteristics of the new device, the Coag-A-Mate MTX® III, are very similar and in most cases they are identical to the Coag-A-Mate MTX® II. The shared technological characteristics of the two systems include the following:

- Both systems are capable of performing coagulation and chromogenic assays.
- Both systems use identical mechanical components, including: all pipetting, disposable manipulation mechanisms, sample handling, liquid level sensing, temperature control, reagent stirring, optical alignments (including optical path, path length), optical detection components, sub-system connectivity (i.e. control cables, control methodologies),
- Both systems use the identical platform layouts and organization.
- Both systems use identical analysis algorithm methodologies.

The only difference is the use of an LED based optical system (as opposed to the previously used halogen lamp based optical system). The LED's provide a more reliable light source and the light provided is filtered so that (as in the previous system) only the appropriate wavelength reaches the cuvette.

Technical Logical Characteristics

The Coag-A-Mate MTX II and Coag-A-Mate MTX III use a photo-optical detection principle. In order to perform the specific assays, there are various reagents and controls that are manufactured to be compatible with the MTX III system. Clot based and chromogenic assays can be run simultaneously in random access. The measuring module consists of the measuring rotor and a photometer. The photometer contains two channels (i.e. two cuvettes can be optically integrated at a time) and each channel consists of 2 LEDs (one for each wavelength), 3 lenses, 405 nm and 570 nm filters, and a photo-detector.

A light beam passes through the cuvette and is received by the photo-detector. As soon as the starting reagent is added to the plasma, the measuring time starts. Any change in the light transmittance is detected and converted into an electrical signal by the photo-detector. When the assay has been completed, the raw data (in seconds for coagulation assays) and in mE/sec (extinction) for chromogenic assays are processed and reported.

The MTX III software controls the mechanical, fluidic, thermal, and optical functions of the instrument so as to accurately manipulate patient fluids, combine the proper reagents with the patient sample in a cuvette ring (which serves as a reaction vessel as well), track patient samples throughout the assay process, integrated the relevant cuvette, and returns a result to the be analyzed by the applicable assay algorithm. The MTX III software also provides the operators with an interface with which the patient information and test results can be managed (on screen and through the LIS as required).

Conclusions from the Clinical Tests

Precision studies to characterize within run and total precision were performed according to guidelines provided in *"Evaluation of Precision Performance of Clinical Chemistry Devices;" National Committee for Clinical Laboratory Standards (NCCLS),* Document EP5-A. The total precision for all assays had a %CV of less than 4%. The results of this experiment demonstrate the Coag-A-Mate MTX III system has comparable precision to that of the Coag-A-Mate MTX II system.

A method comparison experiment, as described in *"Method Comparison and Bias Estimation Using Patient Samples;" National Committee for Clinical Laboratory Standards (NCCLS),* Document EP9-A2, was performed to determine the relationship between results obtained using plasma from normal donors and clinically abnormal specimens for the Coag-A-Mate MTX III and Coag-A-Mate MTX II systems. Testing of samples extended over twenty-two testing days. Each plasma sample

was tested in duplicate. All plasma samples were treated identically with regard to storage and freeze-thaw history. This method comparison study demonstrated that the line of regression at a 95% confidence interval contained the line of identity. The conclusion indicates that there is no statistical difference between the instrument platforms.

The Coag-A-Mate MTX III system demonstrated its ability to determine correct clotting times for samples that had increased levels of interfering substances (lipemia and bilirubin) as described in "*Interference Testing in Clinical Chemistry;" National Committee for Clinical Laboratory Standards (NCCLS)*, Document EP7-A. The clinical samples used in the interference comparison study had noticeable levels of lipemia, bilirubin, or both. The degree of interference substance present was reported as slight, moderate, or marked. When testing samples containing interfering substances the Coag-A-Mate systems showed a high positive correlation (correlation coefficient range 0.889-0.999). This correlation met the acceptance criteria listed in the requirements document for samples with interfering substances. Again, the data generated in this study demonstrated that the Coag-A-Mate MTX III system is equivalent in performance to the Coag-A-Mate MTX II system when testing clinical samples with elevated levels of lipemia and/or bilirubin.

On board stability studies were conducted which also demonstrated that the Coag-A-Mate MTX III system is equivalent in performance to the Coag-A-Mate MTX II.

In conclusion, each of the studies conducted in this clinical trial demonstrated that the overall performance of the Coag-A-Mate MTX III system is equivalent to that of the predicate Coag-A-Mate MTX II system. The Premarket Notification 510(k) presents data in support of Coag-A-Mate MTX III System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

bioMérieux, Inc.
c/o Mr. John Cusack
Sr. Regulatory Affairs Specialist
100 Rodolphe St.
Durham, NC 27712

DEC 2 3 2005

Re: k051030
Trade/Device Name: Coag-A-Mate MTX® III System
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: Class II
Product Code: JPA
Dated: April 18, 2005
Received: April 22, 2005

Dear Mr. Cusack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051030

Device Name: Coag-A-Mate MTX® III

Indications For Use:

This is a multipurpose system for in vitro diagnostic coagulation studies and capable of performing clotting, chromogenic, and immunoassays.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Maria Chan for
Josephine Bautista

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K051030